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Bernadette Verneau

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EXAMINER

KASSA, TIGABU

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,441	Applicant(s) VERNEAU, BERNADETTE	
	Examiner TIGABU KASSA	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/26/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-10 and 12 are pending. Claim 11 remained cancel. Applicant has amended claims 8 and 12. Claims 1-10 and 12 are under consideration in the instant office action. Receipt and consideration of Applicant's amended claim set, and remarks/arguments submitted on 08/26/08 are acknowledged. Applicant's arguments have necessitated new grounds of rejection (e.g. under 35 USC §103(a)). The office action mailed on 05/27/08 is vacated and the time for reply is reset from the mailing of the instant office action.

Claim Objections

The objection of claim 8 is **withdrawn** per applicant's claim amendments removing the table and replacing it with subsections a) to f).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** per Applicant's claim amendments removing the term prevention.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-2, 5-6, 9-10, and 12 under 35 U.S.C. 102(b) as being anticipated by Halvorsen et al (US 2001/0041708) **is withdrawn** per Applicant's arguments that the conjugated linoleic acid/caffeine mass ratio of between 1-15 and 1-6 can not be anticipated by the prior art teachings of mass ratio between 0.005-200 as the earlier are narrower ranges.

Response to Arguments

Applicant's arguments, see pages 4-5, filed 8/26/08, with respect to the rejection of claims 1-2, 5-6, 9-10, and 12 under 35 U.S.C. 102(b) as being anticipated by Halvorsen et al (US 2001/0041708) have been fully considered and are persuasive. The rejection of claims 1-2, 5-6, 9-10, and 12 under 35 U.S.C. 102(b) as being anticipated by Halvorsen et al (US 2001/0041708) has been **withdrawn**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not

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commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 1-2, 5-6, 9-10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halvorsen et al (US 2001/0041708).

Applicant Claims

Applicant claims a composition comprising conjugated linoleic acid and caffeine in mass ratio between 1 and 15 and in further limitation as recited in claim 2 between 1 and 6, which is formulated with an appropriate carrier for use via the oral route in order to loss weight. Instant claim 5 recites possible forms of the composition being in powdered form, in liquid form. Instant claim 9 recites possible administration forms of the composition as dietary supplement, a dietetic composition or a cosmetic composition. Instant claim 10 recites a method of increasing weight loss through administering the claimed composition via the oral route. Instant claim 12 recites a method for treating obesity in a patient comprising administration by the oral route the composition described above.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Halvorsen et al disclose compositions and methods for treating and preventing cellulite by using the composition comprising **conjugated linoleic acid (from about 0.1% to about 10% by weight) (paragraph [0013]) and caffeine (from about 0.05% to 20% by weight) (paragraph [0053])** and other additional ingredients through administration via **the oral route (paragraph [0020] and [0021]) or as topical form or skin care product (paragraph [0021])**. Furthermore, based on calculations done by examiner by converting the disclosed weight % values to mass, the conjugated linoleic acid/caffeine mass ratio is **between 0.005 and 200**, which encompasses the ranges between 1 and 15 and also between 1 and 6 recited in instant claims 1 and 2.

Halvorsen et al disclose different vehicles for delivering the composition which include **liquid or solid emollients, solvents, humectants, thickeners and powders** (paragraph [0038], which addresses instant claim 5.

Halvorsen et al also disclose the composition can be formulated for either **oral administration (paragraph [0020] and [0021]) or topical (cosmetic) (paragraph [0021])** form to be applied to the skin for cellulite prevention or reduction, which addresses instant claim 9.

Halvorsen et al teach the composition is used **to reduce or eliminate cellulite or fat build-ups** through taking an effective amount of the formulation via **the oral route (paragraph [0020])**. Halvorsen et al also disclose methods for treating and preventing cellulite by administering a safe and effective amount of said composition in **topical form (paragraph [0012])**. Additionally, Halvorsen et al disclose that the composition demonstrates a **slimming and “rejuvenating” effects** on appearance (paragraph [0022]), which address instant claims 10 and 12.

*Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)*

Although Halvorsen et al teach a composition comprising **conjugated linoleic acid** and **caffeine** in conjugated linoleic acid/caffeine mass ratio of **between 0.005 and 200** , Halvorsen et al does not explicitly teach the narrow ratios of between 1-15 and 1-6.

*Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)*

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to produce the instantly claimed invention, because Halvorsen et al teach compositions and methods for treating and preventing cellulite by using the composition comprising **conjugated linoleic acid (from about 0.1% to about 10% by weight) (paragraph [0013]) and caffeine (from about 0.05% to 20% by weight) (paragraph [0053])** and other additional ingredients through administration via **the oral route (paragraph [0020] and [0021]) or as topical form or skin care product (paragraph [0021]).** With regard to the conjugated linoleic acid/caffeine mass ratio since the values between 1-15 and 1-6 are encompassed by the values between 0.05-200, a *prima facie* case of obviousness exists when the claimed range lies inside ranges disclosed by the prior art (MPEP 2144.05). An ordinary skilled artisan would have been motivated to have a composition comprising conjugated linoleic acid and caffeine formulated with an appropriate carrier for use via the oral route in order to loss weight , because both conjugated linoleic acid and caffeine are conventionally known weight losing agents. Furthermore, combining two compounds each of which is taught in the prior art to be useful for the same purpose in this case weight loss, in order to form a third

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composition to be used for the very same purpose is straightforward. The idea of combining them flows logically from their having been individually taught in the prior art.” In *re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06). An ordinary skilled artisan would have had a reasonable expectation of success upon following the teachings of Halvorsen et al to produce the instant invention, because both Halvorsen et al teach compositions used **to reduce or eliminate cellulite or fat build-ups** through taking an effective amount of the formulation via **the oral route** (**paragraph [0020]**) and also methods for treating and preventing cellulite by administering a safe and effective amount of said composition in **topical form** (**paragraph [0012]**).

The rejection of claims 1 and 3-8 under 35 U.S.C. 103(a) as being unpatentable over Halvorsen et al (US 2001/0041708) in view of Alviar et al (U.S. patent No. 6,413,545 IDS Reference) **is maintained** for the reasons of record and further articulated and rearranged below in new format.

Response to Arguments

Applicant's arguments filed 8/26/08 have been fully considered but they are not persuasive. Applicants' have traversed the instant rejection by arguing that Halvorsen et al and Alviar et al do not (1) teach or suggest the conjugated linoleic acid/caffeine mass ratio of between 1-15, (2) Alviar et al failed to teach the combination of conjugated linoleic acid and caffeine in a combination, and (3) there is no teaching or suggestions in either Halvorsen et al or Alviar et al to modify or adjust the mass ratio of conjugated

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linoleic acid/caffeine to between 1-15, (4) unexpected result due to synergistic effect imparted by the combination of conjugated linoleic acid and caffeine.

The Examiner respectfully disagrees with Applicant's traversal arguments. Regarding (1)-(3), Halvorsen et al clearly teaches compositions and methods for treating and preventing cellulite by using the composition comprising **conjugated linoleic acid (from about 0.1% to about 10% by weight) (paragraph [0013]) and caffeine (from about 0.05% to 20% by weight) (paragraph [0053])** and other additional ingredients through administration via **the oral route (paragraph [0020] and [0021]) or as topical form or skin care product (paragraph [0021])**. The conjugated linoleic acid/caffeine mass ratio after calculations is between 0.05 to 200, a range which encompasses the narrower range between 1 to 15, wherein *a prima facie* case of obviousness was established since the claimed range lies inside ranges disclosed by the prior art (MPEP 2144.05). Regarding (2) Alviar et al as a secondary reference does not have to teach a composition comprising conjugated linoleic acid and caffeine since this limitation is clearly addressed by the teachings of Halvorsen et al. Regarding (4), Applicant is asserting unexpected result due to synergistic effect imparted by the combination of conjugated linoleic acid and caffeine, applicant only provided a single data point as recited in instant claim 8 where the conjugated linoleic acid/caffeine mass ratio is 5.2 which does not allow the skilled artisan to extrapolate the observed synergism at the high and low points. Examiner would like to see for example at the low end of the mass ratio around 1 and high end of the mass ratio around 15 if the pattern of the claimed synergism exists. The evidence for the synergism effect must be reasonably commensurate in scope with the claimed invention. Therefore, the claimed invention, as a whole, would have

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been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halvorsen et al (US 2001/0041708) in view of Alviar et al (U.S. patent No. 6,413,545 IDS Reference).

Applicant Claims

The claimed subject matters of instant claim 1 are set forth above. Instant claim 3 recites the composition comprises lecithin and colloidal silica. Instant claim 4 recites in further limitation the composition comprises a green coffee extract and/ or chromium chloride. Instant claims 6-7 recite various possible carrier forms for taking the slimming composition like in the form of soluble coffee, tablets, gelatin capsules, capsules or sachets of powder. Instant claim 8 recites in further limitations the contents of the slimming composition caffeine from different sources, conjugated linoleic acid, chromium chloride, and common pharmaceutical and nutraceutical agents lecithin and colloidal silica.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Halvorsen et al are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Halvorsen et al does not explicitly teach the incorporation of the additional ingredients, pharmaceutical excipients, and various possible forms of formulations and

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also the amounts as recited in claims 3-4 and 6-8, respectively. These deficiencies are cured by the teachings of Alviar et al.

Alviar et al disclose a dietary composition effective for managing body weight comprising different supplements including conjugated linoleic acid (column 5, lines 22-33) and a kola nut extract used as a source of caffeine (column 6, lines 5-8), which is formulated with appropriate carriers to be taken through the oral route. Specifically, Alviar et al disclose the additional ingredients, pharmaceutical excipients, and various possible forms of formulations that are recited in claims 3-4 and 6-8 of the instant application as follows:

Alviar et al. '545 discloses the diet composition comprises silicone dioxide fine powder (column 10, Table C) and lecithin (column 11, Table E), which addresses the limitations of instant claim 3.

With regard to instant claim 4 the two ingredients are a source of caffeine and chromium (III), respectively. As it is known by the skilled artisan and also the disclosure by applicant's own specification caffeine and chromium are also weight loss agents, which can be found from different sources, and specifically chromium in different salt forms. Alviar et al also disclose that the diet composition comprises caffeine from kola nut extract (column 6, lines 5-8) and chromium picolinate another salt form of chromium (column 10, Table C), which is a source of chromium.

Note: Examiner interprets “in the form of soluble coffee” as either in liquid or solid form.

Alviar et al disclose that “the diet composition can be produced as **powder, liquid, syrup, emulsion, suspension, and any other available substance to produce**

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finished food products, for example, in the form of biscuits, cakes, cookies, weight loss candy bars, or ingredients of beverages, pasta, or other solid, liquid, or powder carrier for the composition” (column 6, lines 24-40).

Alviar et al disclose the diet composition can be produced in the form of **gelatin capsules, hard capsules, pills, resins,** or any other compressed material. Based on the disclosure in Alviar et al it is possible to interpret that the soluble coffee form as a finished food product either **liquid or solid beverage form.**

Note: Based on calculations performed by examiner in the instant application there are 72 mg of caffeine, 310 mg of conjugated linoleic acid, 0.064 mg of chromium chloride, 30 mg of lecithin, and 30 mg of colloidal silica. If the given weights are converted to % weight there is 10.3% conjugated linoleic acid, 2.4% caffeine, 1% lecithin, 1% colloidal silica, and 0.00042% chromium chloride.

Alviar et al also discloses between **15.5-79.6 % conjugated linoleic acid, 0.38-1.25% caffeine, 0.02-0.11 % chromium picolinate, 0.5% lecithin, and 0.2% colloidal silica by weight.**

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to modify the composition of Halvorsen et al by incorporating instantly claimed invention, because Halvorsen et al teach compositions and methods for treating and preventing cellulite by using the composition comprising **conjugated linoleic acid (from about 0.1% to about 10% by weight) (paragraph [0013]) and caffeine (from about 0.05% to 20% by weight) (paragraph [0053])** and

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other additional ingredients through administration via **the oral route (paragraph [0020] and [0021]) or as topical form or skin care product (paragraph [0021]).** With regard to the conjugated linoleic acid/caffeine mass ratio since the values between 1-15 and 1-6 are encompassed by the values between 0.05-200, *a prima facie* case of obviousness exists when the claimed range lies inside ranges disclosed by the prior art (MPEP 2144.05). An ordinary skilled artisan would have been motivated to have a composition comprising conjugated linoleic acid and caffeine formulated with an appropriate carrier for use via the oral route in order to loss weight , because both conjugated linoleic acid and caffeine are conventionally known weight losing agents. Furthermore, combining two compounds each of which is taught in the prior art to be useful for the same purpose in this case weight loss, in order to form a third composition to be used for the very same purpose is straightforward. The idea of combining them flows logically from their having been individually taught in the prior art.” In *re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06). An ordinary skilled artisan would have had a reasonable expectation of success upon following the teachings of Halvorsen et al to produce the instant invention, because both Halvorsen et al teach compositions used **to reduce or eliminate cellulite or fat build-ups** through taking an effective amount of the formulation via **the oral route (paragraph [0020])** and also methods for treating and preventing cellulite by administering a safe and effective amount of said composition in **topical form (paragraph [0012]).**

It would have been prima facie obvious to modify the caffeine and CLA composition taught by Halvorsen et al. by adding lecithin and colloidal silica as taught, because Alviar et al teaches the incorporation of lecithin and colloidal silica as described

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above. An ordinary skilled artisan would have been motivated to incorporate lecithin and colloidal silica, because lecithin and colloidal silica are conventional ingredients added during formulating compositions. Furthermore, as it is described (The Merck Index definition, Fourteenth Edition) lecithin is a conventional ingredient used as digestible surfactant and emulsifier of natural origin and colloidal silica is also a conventional surfactant used for flocculating, coagulating, dispersing, stabilizing etc (<http://www.azom.com/details.asp?ArticleID+1385>). An ordinary skilled artisan would have had a reasonable expectation of success upon combining the prior arts, because both Halvorsen et al and Alviar et al teach similar compositions for the same intended purpose namely weight loss.

It would have been prima facie obvious to modify the composition of Halvorsen et al by adding a green coffee extract which is a source of caffeine and chromium chloride as source of chromium, because Alviar et al teach the incorporation of a caffeine and chromium in the composition as discussed above. An ordinary skilled artisan would have been motivated to incorporate green coffee extract as source of coffee and salt of chromium as source of chromium, because these ingredients are conventional sources of caffeine and chromium, which are also known weight loss agents too. Chromium chloride is one salt form of chromium, which also can be replaced by other salts like chromium picolinate in Alviar et al. Furthermore, combining two compounds each of which is taught in the prior art to be useful for the same purpose in this case weight loss, in order to form a third composition to be used for the very same purpose is straightforward. The idea of combining them flows logically from their having been individually taught in the prior art.” In *re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (see

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MPEP 2144.06). One of ordinary skill in the art at the time of the instant application was filled would have had a reasonable expectation of success in upon combining the prior arts, because both Halvorsen et al and Alviar et al teach similar compositions for the same intended purpose namely weight loss.

It would have been prima facie obvious to modify the composition of Halvorsen et al by having slimming composition comprising conjugated linoleic acid, caffeine, lecithin, chromium chloride, and colloidal silica, because Alviar et al teach weight loss compositions comprising conjugated linoleic acid, caffeine, lecithin, chromium, and colloidal silica. Specifically linoleic acid, caffeine, chromium are art recognized weight loss agents and colloidal silica and lecithin are conventional formulating surfactants. With regard to instant claim 8 it is within the purview of the skilled artisan to optimize the concentration of each of the components in the composition. An ordinary skilled artisan would have been motivated to incorporate green coffee extract as source of coffee and salt of chromium as source of chromium, because linoleic acid, caffeine, chromium are art recognized or commonly known weight loss agents and colloidal silica and lecithin are conventional formulating surfactants. Additionally, it is within the purview of the skilled artisan to optimize the concentration of each of the components in the composition. Furthermore, combining compounds each of which is taught in the prior art to be useful for the same purpose in this case weight loss, in order to form a third composition to be used for the very same purpose is straightforward. The idea of combining them flows logically from their having been individually taught in the prior art.” In *re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06). One of ordinary skill in the art at the time of the instant application was

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filled would have had a reasonable expectation of success upon combining the prior arts, because both Halvorsen et al and Alviar et al teach similar compositions for the same intended purpose namely weight loss.

Conclusion

Claims 1-10 and 12 are pending. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

11/21/08

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616

